DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
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Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

July 23, 1999

Ref: 99-DAL-WL-22

WARNING LETTER

FEDERAL EXPRESS

Richard J. Lee, Owner
2130 Thomas Road
Booneville, AR 72927

Dear Mr. Lee:

An inspection of your rabbit growing operation conducted November 17, 1998, confirmed that you offered an animal for sale for slaughter as food in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), and you have caused animal drugs to become adulterated within the meaning of Section 501(a)(5) of the Act.

Our inspection followed USDA's notification of a violative Streptomycin residue in an animal which you offered for slaughter. Our investigator found that you hold animals under conditions which are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that rabbits have been treated only with drugs which have been approved for use in those species; for assuring that drugs are used in a manner not contrary to the directions contained in the labeling; and for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit the depletion of potentially hazardous residues of drugs from edible tissues. Food from animals held under such conditions is adulterated within the meaning of Section 402(a)(4) of the Act.

Further, our investigation found that rabbits medicated by you with the drug Corid (Amprolium) were offered for slaughter as food at Pel-Freez Rabbit Meat, Inc., located at 404 N. Arkansas St. Rogers, AR 72757, on July 5, 1998. You have adulterated the drug Corid (Amprolium), that your firm uses on rabbits, within the meaning of Section 501(a)(5) of the Act, when you failed to use the drug in conformance with its approved labeling. Your use of the drug, in a species for which it is not approved, causes the drug to be unsafe for use within the meaning of Section 512 of the Act. Our investigator also found that you were using Terramycin to treat your rabbits which is labeled for use in cattle, sheep, swine, honey bees, chickens, and turkeys.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

As a producer, you should take precautions such as:

1. Using drugs in your rabbits in a manner consistent with their labeling and/or consulting a licensed veterinarian before treating your herd with drugs.

2. If the animal has been medicated, implementing a system to withhold the animal from slaughter for an appropriate period of time to deplete potentialy hazardous residues of drugs from edible tissue. If you do not want to hold the medicated animal then it should not be offered for human food, and it should be clearly identified and sold as a medicated animal.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug, and Cosmetic Act. The fact that you may have caused the adulteration of an animal that was sold to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

Within 15 working days of receipt of this letter, notify this office in writing of the specific steps you have taken to correct these violations, including an explanation of each step being taken to prevent the recurrence of the violation. If corrective action cannot be completed within 15 days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made. Your reply should be addressed to the Food and Drug Administration, Attention: Todd W. Cato, Compliance Officer.

Sincerely,

Robert J. Dunniger for

Joseph R. Baca
District Director